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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

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Please find below and/or attached an Office communication concerning this application or proceeding.

3762

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10 July 2006 have been fully considered but they are not persuasive. Claims 1-28 stand rejected under 35 U.S.C. §102(b) as being anticipated by Stoop et al. Applicant argues that Stoop et al. does not disclose determining a difference between morphologies of at least 2 PVCs. However, by Applicant's own admission at the top of page two of the correspondence filed 10 July 2006, certain embodiments of Stoop et al. do consider T-wave morphology in performing calculations to determine whether to deliver preventative therapy. Therefore, Examiner maintains that the original rejection for arguments made of record and restated below is proper, as Stoop et al. clearly discloses using a difference in morphologies to determine whether to deliver preventative therapy (column 2, lines 10-50), since the time derivative curve of T-wave amplitude morphology as taught by Stoop et al. is nonetheless a measure of signal morphology. Although a T-wave follows the first contraction, it also precedes any subsequent PVCs, and in this way influences and is related to a PVC.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3762

2. **Claims 1-28 stand rejected** under 35 U.S.C. 102(b) as being anticipated by Stoop et al. (US Patent 6,370,431).

Regarding claims 1-12 and 23-28, Stoop et al. discloses a method of detecting and preventing ventricular arrhythmias comprising detecting at least two PVCs, determining a difference between their morphologies, and comparing said morphology difference to a predetermined threshold to determine whether to deliver preventative therapy (column 2, lines 10-50); further comprising a step of determining a difference between the coupling intervals of the at least two PVCs and comparing the difference to a predetermined threshold to determine whether to deliver preventative therapy (column 9, line 47 through column 10, line 10); further comprising a step of adjusting the threshold values based on recently detected physiological events (column 5, line 45 through column 7, line 59; column 10, lines 48-54); and delivering preventative therapy in the form of overdrive pacing when the analysis of the PVC parameters indicates that therapy should be delivered (column 2, lines 42-50; column 10, lines 11-54).

Further regarding claims 9 and 10, Stoop et al. states the coupling interval as referring to "the interval from the prior R wave to the VES to the current QT interval," (column 9, lines 60-62) where the term QT "embraces both the QRS portion and T wave portion of the ventricular signal" (column 3, lines 60-63). It is understood that this is a disclosure of R-R coupling intervals. However, as seen in Fig. 1 the disclosed device of Stoop et al. also comprises P-wave sense circuitry (25) and, so long as the definition of coupling interval remains consistent, would be capable of using P-R intervals instead of the stated R-R intervals for a functional equivalent result well known in the art.

Further regarding claim 11, Stoop et al. discloses a method for obtaining depolarization information for the current cycle and comparing it to the template generated during the learning phase which involves compiling values of the QT dispersion in different rate bins and determining the difference of respective wave form amplitudes along successive time increments by subtracting amplitude values and integrating over the time domain (column 5, line 66 through column 6, line 17). It is well known that the time integral of a curve in the Cartesian plane is the mathematical equivalent to the area under said curve, and a subtraction of the time integral of one curve (e.g. the current QRS waveform) from that of another (e.g. a stored template) is representative of the difference of the areas under those curves. Therefore, Stoop et al. is understood to disclose a method of analyzing the morphology of the current QRS complex with a previously stored template (which is based on at least 2 previous measurements) by means of comparing the difference in areas under the current waveform and stored template (Figs. 4A-D and 5A-D). Stoop et al. further discloses weighting the results obtained for use in the subsequent determination of intervention (column 9, lines 20-46; column 10, lines 11-34), which is taken to be an equivalent step to assigning a match score that is proportional to the difference in areas under the compared QRS curves.

Regarding claims 13-22, Stoop et al. discloses an apparatus (Fig. 1, pacemaker system) configured to detect and prevent ventricular arrhythmias comprising a detecting means or sensing circuit (sense circuits 24-26) for detecting at least two PVCs; a processing means (signal processor 27, control microprocessor 20)) for determining

morphological and coupling interval differences; a comparing means to compare said differences to predetermined thresholds; and a delivery means or pacing circuit (ventricular and atrial pulse generators 15 and 18) for delivering preventative therapy based on said comparisons. (Column 4, lines 7-41).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
21 September 2006


George Manuel
Primary Examiner